II. REMARKS

A. Status of the Claims

Claims 31-51 were pending at the time of the Action. Claims 33 and 35-43 have been withdrawn. Accordingly, claims 31, 32, 34, and 44-51 were examined in the Action. Claim 48 has been amended to independent format. Accordingly, the claims from which claim 48 previously depended (*i.e.,* claims 31 and 44) have been cancelled. Claim 48 has also been amended to include the limitation that the vaccine composition does not contain a whole-cell lysate of a Borrelia pathogen. Support for this limitation can be found in the Specification at page 7, lines 8-18. Negative limitations can be used in patent claims (MPEP § 2173.05(i)). Additionally, claims 32-38 and 45-47 have been cancelled. New claims 88-91 have been added. Withdrawn claims 40-43 have been amended to conform with the amendments made to the claims currently under examination. No new matter was added by these amendments. Thus, claims 40-43, 48, and 88-91 are pending, and claims 48 and 88-91 are currently under examination.

B. Objections to the Specification

The Action objected to several informalities in the disclosure. Applicants note that "Riechmann et al., 1988" is in the literature cited. Applicants have addressed the remaining objections in the amendments to the specification included herewith. Applicants, therefore, request the withdrawal of these objections.

C. The Rejections Under 35 U.S.C. § 112 Are Overcome

The Action asserts that claims 45, 46, and 47 are indefinite because it is unclear what is meant by "different" Borrelia antigens or fragments thereof. Applicants traverse this rejection.

The meaning of the term "definite" is clear to a person of ordinary skill in the art in light of the disclosure in the present specification. For example, the specification discloses that

"vaccines may contain a mixture of different antigens derived from the same or different pathogens." (p. 31, ln. 9-10). As would be understood by those in the art, the "different" *Borrelia* antigens or fragments recited in claims 45, 46, and 47, thereof refer to antigens that are different from each other and that may be from either the same *Borrelia* species or from different *Borrelia* species. Applicants note, however, that claims 45-47 have been cancelled rendering this rejection moot.

For the reasons above, Applicants request the withdrawal of this rejection.

D. The Claims Are Novel Over the Cited Art

1. The Claims Are Novel Over the '829 Patent

The Action rejects claims 31, 32, 34, and 44-47 as being anticipated by U.S. Patent No. 5,582, 829 (the '829 patent). Applicants traverse this rejection.

The Action states that the '829 patent teaches a vaccine composition comprising a sonicated preparation of whole bacteria. As described on pages 6 and 7 of the present specification, Borrelia infection can induce an autoimmune response in affected hosts, which can lead to chronic arthritis and other complications. Several Borrelia antigens have been identified as the likely cause of host self-reactivity (Specification, p. 7, ln. 14-16). Like Borrelia infection, whole-pathogen formulations from Borrelia also induce an autoimmune response in the subject (Specification, p. 7, ln. 9-18). Accordingly, safety concerns make whole-cell preparations of Borrelia vaccines unsuitable. The presently claimed invention overcomes the problems associated with whole-pathogen Borrelia vaccine compositions.

The current claims depend from claim 48, which was not rejected as anticipated by the '829 patent. In addition, current claim 48 further clarifies that the claimed vaccine composition does not contain a whole-cell lysate of a Borrelia pathogen. For at least these reasons, the

current claims are novel over the '829 patent. Applicants, therefore, request the withdrawal of this rejection.

2. The Claims Are Novel Over the '512 Patent

The Action rejects claims 31, 32, 34, and 44-47 as being anticipated by U.S. Patent No. 5,688,512 (the '512 patent). Applicants traverse this rejection.

The Action states that the '512 patent teaches a vaccine composition comprising substantially pure OspA from two or more strains of *B. burgdorferi* and an immunologically acceptable carrier or a vaccine composition comprising fractions B, C, and E or combinations thereof together with an immunologically acceptable carrier. The Action has not established, however, that the '512 patent teaches a vaccine composition containing a Borrelia antigen having an amino acid sequence as defined in current claim 48. Applicants, therefore, request the withdrawal of this rejection.

3. The Claims Are Novel Over the '914 Patent

The Action rejects claims 31, 32, 34, and 44-47 as being anticipated by U.S. Patent No. 6,113,914 (the '914 patent). Applicants traverse this rejection.

The Action states that the '914 patent teaches a vaccine composition comprising at least two purified OspA proteins from different *B. burgdorferi* subgroups in an admixture with a suitable carrier. The Action has not established, however, that the '914 patent teaches a vaccine composition containing a Borrelia antigen having an amino acid sequence as defined in current claim 48. Applicants, therefore, request the withdrawal of this rejection.

4. The Claims Are Novel Over Choi et al.

The Action rejects claim 31, 32, 34, and 44-51 as being anticipated by Choi *et al.* (WO 98/59071). Applicants traverse this rejection.

A claim cannot be anticipated by a reference if the allegedly anticipatory disclosure is not enabled. Mere naming or description of the subject matter is insufficient if it cannot be produced without undue experimentation. MPEP § 2101.01. The disclosure in Choi is insufficient to enable the presently claimed invention. Choi appears to describe a *B. burgdorferi* sequencing project. While Choi discloses hundreds of sequences reportedly obtained from *B. burgdorferi*, it fails to disclose a single example where even one of these sequences was used to elicit an immune response in an animal.

As described in the background of the present specification, there have been difficulties associated with immunization against Borrelia. For example, antibodies against a number of *B. burgdorferi* antigens have been found to cross-react with host nerve cell axons, synovial cells, hepatocytes, and cardiac muscle proteins (Specification, p. 7, ln. 12-14). Thus, making whole-cell vaccines or vaccines with certain cross-reactive antigens undesirable. The concern of vaccine-induced autoimmunity has focused the development of a vaccine for human Lyme disease on a subunit rather than whole-cell design (Specification, p. 7, ln. 16-18). However, only one FDA licensed vaccine against Borrelia (LYMErix), which is comprised of recombinant OspA, has been developed (Specification, p. 7, ln. 24). LYMErix was eventually pulled from the market (Specification, p. 8, ln. 30 to p. 9, ln. 2).

Choi has done nothing more than venture a guess that some of the hundreds of *B. Burgdorferi* genes or gene fragments that were sequenced and listed in Table 1 would be useful antigens. This does not provide an enabling disclosure of the presently claimed vaccine, particularly given the art-recognized challenges associated with identifying effective *Borrelia* antigens that do not induce an autoimmune reaction in the host. Applicants, therefore, request the withdrawal of this rejection.

E. Conclusion

For the reasons set forth above, Applicants believe that the claims are in condition for allowance. Accordingly, Applicants request that the species restriction be withdrawn and that the previously non-elected species be entered in the case.

The Examiner is invited to contact the undersigned attorneyat 512-536-5654 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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